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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/717,746	11/20/2003	Jerry Loren McLaughlin	33724/6	8781

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EXAMINER

KIM, VICKIE Y

ART UNIT PAPER NUMBER

1618

DATE MAILED: 11/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/717,746

Applicant(s)

MCLAUGHLIN ET AL.

Examiner

Vickie Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 1-6 and 10-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 7-9 and 15-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>5/31/2005</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Election acknowledged

1. Applicants' election the invention group II of claims 7-9 is acknowledged. The restriction is made without traverse. Therefore, the restriction requirement is deemed to be proper and made FINAL.

Status of Application

1. Acknowledgement is made of amendment filed 8/21/06. Upon entering the amendment, the claims 7-9 are amended and claims 15-20 are newly added. Since newly added claims are drawn to patentably non-obvious variant with the elected invention, the claims 7-9 and 15-20 will be examined together and presented for the examination.

2. All remaining claims not drawn to the elected invention are withdrawn from further consideration as being non-elected. The following rejections are made.

Information Disclosure Statement (IDS)

The information disclosure statement (IDS) is submitted on 5/31/05. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner. Please refer to applicants' copy of the 1449 submitted herewith.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 7-9 and 15-20 are rejected under 35 U.S.C. 102(b) as being anticipated by McLaughlin et al(US 5717113 or “evaluation of the Pawpaw tree, Asimina....”, 1993).

5.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 7-9 and 15-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ratnayake et al(“evaluation of the Pawpaw tree, Asimina....”, 1993). McLaughlin et al(US 5717113)

The claims are drawn to a method for extracting a crude extract, comprising the steps as recited in claims 7 or 15.

The steps are comprising :

(a) obtaining manufacturing materials (e.g. twing or bark) from natural plant sources such as Asinima,Goniothalamus, Annoa, etc;

(b) air dry;

(c) sieve;

(d) pulverizing to form pulverized product;

- (e) water and ethanol extraction;
- (f) ethanol(alcohol) extraction in a percolator;
- (g) concentrating to form syrup;
- (h) separate a crude extract from water extract and spray dry and make the end product(capsule or tablet, etc).

7.

8. Claims 7-9 and 15-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over McLaughlin et al(US 5717113) in view of Ratnayake et al("evaluation of the Pawpaw tree, Asimina....", 1993).

The claims are drawn to a method for extracting a crude extract, comprising the steps as recited in claims 7 or 15.

The steps are comprising :

- (a) obtaining manufacturing materials (e.g. twig or bark) from natural plant sources such as Asinima, Goniiothalamus, Annoa, etc;
- (b) air dry;
- (c) sieve;
- (d) pulverizing to form pulverized product;
- (e) water and ethanol(alcohol) extraction in a percolator;;
- (f) concentrating in vacuum to form syrup;
- (g) separate a crude extract from water extract by removing water layer; and
- (h) spray dry and make the end product(capsule or tablet, etc).

McLaughlin et al(US'113, hereinafter) teach a method obtaining novel acetogenins, and goniocins isolated from *Asimina* or *Goniothalamus*, see abstract and full text.

Throughout the disclosure, US'113 teaches extraction, fractions and isolation process where detailed procedures for obtaining crude extracts from each plant material including the bark of *Asimino triloba* or *Goniothalamus giganteous* were taught. For instance, at col. 21 and 28-29, US'113 teaches most of the critical elements required by the instant claims such as air dried(b), pulverized stem bark(d), crude extract(h), 90% or 95% ethanol extract(e) and vacuum evaporated to make concentrate and yield a crude extract(f-g).

As to element (h), US'113 , at Col. 4, teaches unit dosage forms for various routes of administration such as capsule or tablet dosage forms for oral administration, see lines 56-61. The components (a-b), (d-h) are well taught.

It is noted that the component (e) such as water extraction has not been specification mentioned. However, since ethanol used for extraction is not 100% ethanol, therefore, there was some water content and the component (e) is inherently possessed by US'113 patent. Additionally, water removal from concentrate or spray drying to facilitate the encapsulation of tableting is commonly practiced in pharmaceutical field when the tablet or capsule is formulated and thus the claims are not patentably distinct over the prior art where McLaughlin, at col.4, lines 56-67, already recognizes the manufacturing tablet and capsules as conventional.(see PTO-892 for supporting documents to show conventional knowledge regarding spray drying to facilitate

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encapsulation and tableting). As evidenced by numerous documents available in the art, the said differences are considered to be minor and do not render the claims patentable over the prior art of the record.

As to the component (c), although the sieved product has not been mentioned, however, it would have been obvious to one of ordinary skill in the art to modify McLaughlin's teaching to sieve the plant materials to enhance the efficacy when McLaughlin is taken in view of Ratnayake's published document(1993) because Ratnayake teaches the component (c) where the sieved product has higher yield of final product of crude extract(see pages 4 of 9, second paragraph).

Ratnayake's published document(1993) teaches the potent antitumour, pesticidal or insecticidal plant extract such as F005, Acetogenins(Annonaceous acetogenins) and the extracts, fractions and isolates obtained from the plant materials such as Asimina triloba (pawpaw tree) in addition to the component (c) as mentioned earlier to yield crude extract having better quality(see page 4 of 9, second paragraph).

As to claims 8-9 and 20, Ratnayake's teaches the LC50 values ranging from 0.04-0.36(see table 2, page 7 of 9). Furthermore, both references teach Brine Shrimp Test(BST) LC50 as a standard test to measure the effectiveness and toxicities. Thus, all the claims are prima facie obvious and the claims are not patentably distinct over the prior art when McLaughlin is taken in view of Ratnayake. One would have been motivated to make such modification because one could increase industrial value and applicability by make such modification (e.g. reduction of cost or better quality of product with high concentration, etc).

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One would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same ingredients and share common utilities, and pertinent to the problem which applicant concerns about. MPEP 2141.01(a).

Conclusion

1. No claim is allowed.
2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 571-272-0579. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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VICKIE KIM

PRIMARY EXAMINER

Vickie Kim

November 10, 2006

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